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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/741,881	12/22/2000	Norman G. Anderson	2316-143	5632

7590 08/05/2004

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EXAMINER	
PADMANABHAN, KARTIC	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 08/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/741,881	ANDERSON, NORMAN G.	
	Examiner	Art Unit	
	Kartic Padmanabhan	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 28-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 28-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-10 and 28-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 1 is rejected as vague and indefinite for the recitation of "capable" because it has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

4. Claim 1 is rejected as vague and indefinite for the recitation of a second solid phase because it is unclear if the second slanted solid phase is a component of the same sedimentation container as the first solid phase or if it is part of a different container altogether.

5. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step is how the particles are sedimented across a second slanted solid phase when they have already been sedimented across a first slanted solid phased. In other words, does resuspension or some other process take place before the particles are sedimented for the second time? Also, applicant should change "respected" to "respect" in line 13 of the claim.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1-10 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suovaniemi (US Pat. 4,290,997) in view of Anderson et al. (US Pat. 6,254,834).

Suovaniemi teaches a method and apparatus for measurement of agglutination tests, wherein the reaction vessel may be a cuvette that is made such that its bottom is at an angle. The measuring vessels may be separate cuvettes or may be a matrix of several cuvettes, which matrix can be made by transfer molding out of plastic, like the cuvette block of the FP-9 system (Col. 4, lines 18-34). When sample is added to the cuvette, non-agglutinated particles are sedimented in the bottom of the cuvette; however, agglutinated particles are found along the whole length of the slanted bottom of the cuvette (Col. 5, lines 20-28 and Fig. 6). Further, the slanted portion of the cuvette may have specific antigens or antibodies attached thereto, such that the agglutination complexes adhere more firmly to the cuvette surface. Coloring or fluorescent agents, or any

other measurable agent may also be added to the agglutination complex (Col. 4, lines 4-12). The complexes are then detected. The method of the reference allows for the measurement of the results of various agglutination tests. The method of the reference is performed with red corpuscles; however, the reference states that agglutination tests are routinely performed with bacteria and viruses (Col. 1). The reference does not teach the use of an additional slanted solid phase to sediment the particles.

Anderson et al. teach methods for the detection and characterization of microorganisms using sedimentation rate and binding density. The method comprises ultracentrifugation of a sample containing the microorganisms in an ultracentrifuge tube to concentrate them. This ultracentrifugation step may include the formation of density gradients and/or the staining of the microorganisms using fluorescent dyes (Col. 5, lines 1-19). The centrifuge tube of the reference has a slanted bottom surface, as seen in Figures 2A-2C. The method of the reference may also include the step of exposing the microorganisms to reagents, including detergents, surfactants, and enzymes, contained and immobilized in distinct zones in a density gradient to dissolve contaminating particles (col. 6, lines 42-50). In addition, fluorescent particles of known density may be included in the sample to assist in identifying particles by density (Col. 13, line 65 – Col. 14, line 10). However, the reference only teaches restricting the movement of reagents within the second slanted solid phase and does not teach reagent immobilization.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to concentrate the particles of interest over a slanted solid phase prior to detection as in Anderson et al. with the method of Suovaniemi, as this would allow for greater binding efficiency. One of skill in the art would have known that the greater the concentration of target

analyte in a given area, the greater the binding efficiency to any binding agents they contact, which would allow for easier detection. Further, by concentrating the particles as in Suovaniemi and then immobilizing the particles to the solid phase via their specific receptors, one would have been able to eliminate interferants and achieve more reliable detection of target analytes. Although Anderson does not specifically teach immobilization of the reagents, by immobilizing versus mere containment in an area, one would have achieved greater binding efficiency. In addition, it would have been obvious to stain the particles because Suovaniemi states that any detectable agent may be added to the complex.

Response to Arguments

9. Applicant's arguments filed 7/20/04 have been fully considered but they are not persuasive.

10. Applicant argues that Suovaniemi fails to teach concentrating reacting/agglutinating cells along the slanted solid phase. This is not found convincing because the cells of interest are originally in free form in the sample liquid, and are subsequently concentrated onto the slanted solid phase and out of solution.

11. Applicant also argues that Suovaniemi requires the agglutinated cells to be spread over the entire surface of the solid phase to be operable. This is also found unconvincing. The reference teaches that antigens or antibodies for the agglutination complex may be attached to the solid phase, in which case the "agglutination complex adheres to the cuvette wall or bottom..." (Col. 4, lines 4-9). As such, there is no requirement that the cells me spread over the entire surface of the slanted solid phase.

12. Applicant then argues that Suovaniemi fails to teach centrifugation, but the secondary reference, Anderson, is relied upon for this teaching. Applicant's argument that using centrifugation with the method of Suovaniemi makes the method of Suovaniemi inoperable is off point. Depending on the analyte of interest (microorganisms in the case of Anderson), one of ordinary skill in the art would have known the best method (gravity or centrifugation) of sedimentation. Applicant also argues that the method of Suovaniemi would be inoperable with a density gradient, but has not provided any basis for this assertion, which renders the position prima facie unconvincing.

13. Applicant argues that Anderson, as a secondary reference, does not teach sedimentation on a slanted surface in the middle of the vessel; however, the claims in now way require sedimentation in the middle of the vessel. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

14. Applicant's arguments that Suovaniemi and Anderson are at odds with each other because one attempts to spread out agglutinated particles, while the other attempts to concentrate them are not convincing. Suovaniemi does not require the particles to be spread out. In any case, Suovaniemi represent the first step in which particles are taken out of solution and bound to a first slanted solid phase, and Anderson represents the second step in which the particles are bound by their receptor on another solid phase to allow for detection.

15. Applicant argues that there is no mention in the references of having binding agents immobilized on a small distinct part of the surface; however, Suovaniemi teaches that reagents may be immobilized on the bottom of a cuvette, and Anderson teaches that reagents may be

contained within small distinct zones. Further, the claims do not require immobilization on a small part of the solid phase. Applicant also argues that there is no mention of using plural binding agents, each specific to different species of particles, as in claim 2; however claim 2 only requires plural binding agents, which the references clearly teach. There is no requirement of plural different binding agents or binding to different species of particles. Applicant argues that there is no mention of different regions of the solid phase having different binding reagents, but Anderson teaches different reagents within different zones, and one would have been able to immobilize the reagents instead of mere containment with a reasonable expectation of success. Applicant argues that the first and second slanted solid phases never have different binding agents. This is not convincing because multiple analytes may be bound, and although the receptors for one specific analyte may be the same in both solid phases, different analytes require different receptors, which would meet the limitation of a different receptor in each solid phase. Applicant's argument that a binding agent is never added to the particles is also unconvincing because the particles may be stained, for which binding must occur. Finally, applicant argues that both slanted surfaces do not cross a single path, but since the particles of interest are first concentrated by the method of Suovaniemi and then detected using the protocol of Anderson, the limitation of claim 30 requiring a particle to pass through both solid phases is deemed met.

Conclusion

Claims 1-10 and 28-30 are rejected.

Reference: Takekawa is cited as art of interest for teaching a method of measuring agglutination.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 571-272-0825. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kartic Padmanabhan
Patent Examiner
Art Unit 1641

*** KP

BAO-THUY L. NGUYEN
PRIMARY EXAMINER
8/3/04